

REMARKS

This communication is responsive to the Office Action dated March 17, 2009. Applicants respectfully request entry of the foregoing amendments and reconsideration of the application in view of the foregoing amendment and the following remarks.

I. Amendment to the specification

The title is amended to reflect the claimed subject matter, as requested in the Office Action at page 2. No new matter is added.

II. Amendment to the claims

Claims 30, 32, 33, 37 and 40 were previously withdrawn pursuant to an election of species. Applicants respectfully request rejoinder and examination of the withdrawn claims upon identification of allowable subject matter in generic or linking claims.

Claims 1-14 were previously cancelled, and claims 15-28 are now cancelled. Claim 29 is amended. No new matter is added.

The foregoing amendments are made solely to advance prosecution and not in acquiescence to any rejection or objection. Applicants reserve the right to pursue any subject matter removed by amendment in continuing applications with the same right of priority as the present application.

Following entry of the foregoing amendments, claims 29-42 are pending, and claims 29, 31, 34-36, 38, 39, 41 and 42 are under examination. Claim 29 is the sole independent claim under examination.

III. Election of species

Page 2 of the Office Action notes an error in the status of claims 29 and 30. Applicants thank the Examiner for pointing out this error, which has been corrected in the present listing of claims.

IV. Objections to the title

In view of the amendment to the title, Applicants respectfully request withdrawal of the objection to the title, listed at page 2 of the Office.

V. Rejections under the enablement provision of 35 U.S.C. § 112, first paragraph

A. “Preventing”

At pages 2-3 of the Office Action it is asserted that claims 15, 17, 21-22, 24, 25, 27-29, 31, 34-36, 38, 39, 41 and 42 exceed the scope of enablement provided by the specification for recitation of a method of “preventing” vasculitis. The cancellation of claims 15, 17, 21-22, 24, 25, 27 and 28 renders moot the rejection of those claims. As to claims 29, 31, 34-36, 38, 39, 41 and 42, Applicants respectfully traverse. However, solely to advance prosecution, and not in acquiescence to the rejection, claim 29 is amended to delete recitation of “preventing.” Claims 31, 34-36, 38, 39, 41 and 42 depend from claim 29. Accordingly, Applicants respectfully believe that the rejection is overcome and should be withdrawn.

B. Deposit requirement

At pages 3-4 of the Office Action it is asserted that claims 25, 28, 39 and 42 are not enabled because a statement concerning the deposit requirement has not been made. Applicants provide, herewith, copies of the deposit receipts, and a declaration by the undersigned representative. Applicants respectfully believe that all requirements under 37 C.F.R. § 1.808 are met and that the rejection is overcome and should be withdrawn.

VI. Rejections under 35 U.S.C. § 102

At page 4 of the Office Action it is asserted that “the claims” are anticipated by U.S. Patent No. 5,817,790 (“the ‘790 patent”). At page 5 of the Office Action, it is alleged that claims 15, 17, 20-22, 24, 25, 27-29, 31, 34-36, 38, 39, 41 and 42 are anticipated by U.S. Patent No. 5,888,510 (“the ‘510 patent”). The cancellation of claims 15, 17, 20-22, 24, 25, 27 and 28 renders moot the rejection of those claims. As to claims 29, 31, 34-36, 38, 39, 41 and 42, Applicants respectfully traverse.

To the extent that the rejections depend on recitation of “preventing” vasculitis, this basis of rejection is no longer applicable in view of the amendment to claim 29, made solely to advance prosecution.

As to any remaining basis of rejection, it is noted that both the ‘510 and ‘790 patents disclose antibodies against the IL-6 receptor, but neither patent recites a *method* of treating polyarteritis nodosa, or vasculitis in general, nor even recite these terms.

An assertion of anticipation, therefore, necessarily requires that no weight be accorded to the preamble recitation of a “method of treating vasculitis.” In this vein, the Office Action states at page 5, in regard the ‘510 patent, that “[t]he recitation in the pending claims that the agent is intended to treat vasculitis, particularly polyarteritis nodosa, is given weight only to the extent that the product must be usable for such; the reference does not have to teach that particular use.” *See also*, page 4, in regard the ‘790 patent.

In view of current case law, however, the preamble does have patentable weight. The recitation of “a method of treating vasculitis” must be seen in the context of the body of the claim which recites “administering...to a subject in need thereof,” and also in light of the Federal Circuit’s 2001 holding in *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001). The *Rapoport* holding was summarized as follows in *Jansen v. Rexall Sundown*, 342 F.3d 1329 (Fed. Cir. 2003):

A similar issue arose in *Rapoport*, an interference proceeding before the PTO’s Board of Patent Appeals and Interferences. The count in that case read as follows:

A method *for treatment of sleep apneas* comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof *to a patient in need of such treatment*

254 F.3d at 1056 (emphases added). On appeal we gave weight to the ordinary meaning of the preamble phrase “for treatment of sleep apneas,” interpreting it to refer to sleep apnea, *per se*, not just “symptoms associated with sleep apnea.” *Id.* at 1059. Rapoport argued that the count was unpatentable on the ground that a prior art reference disclosed that a form of the compound

recited in the claim could be administered, not for treatment of sleep apnea itself, but for treatment of anxiety and breathing difficulty, a symptom of apnea. *Id.* at 1061. We rejected that argument, stating, “There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition.*” *Id.* (emphasis added). Thus, the claim was interpreted to require that the method be practiced with the intent to achieve the objective stated in the preamble.

Jansen 342 F.3d 1329. (Bold emphasis added). It is clear that *Jansen* and *Rapoport* apply to the present claims. The recitation of “in need thereof” indicates that the method of claim 29 is “practiced with the intent to achieve the **objective** stated in the preamble,” *Jansen* 342 F.3d 1329, emphasis added.

To be “practiced with the intent to achieve the objective stated in the preamble,” *id.*, requires that the claimed IL-6 antagonist be administered to a patient with vasculitis, with the specific intent that such administration be effective for the treatment of vasculitis. There can be no intent without knowledge. Such a specific intent requires (a) knowledge that the patient has vasculitis and (b) knowledge that an IL-6 antagonist is effective in treating vasculitis. For the art to read on such a claim, therefore, it would have to provide such knowledge to the person of ordinary skill in the art at the time of filing the application. The art does not provide such knowledge, or evidence that this knowledge existed, at the time of filing the application.

Therefore, the rejection over the ‘510 and ‘790 patents entirely relies on a misconstruction of the claims. If claim 29 is construed according to the entire language of the claim, and in view of *Jansen* and *Rappoport*, it is not anticipated by the cited art. Since claims 31, 34-36, 38, 39, 41 and 42 depend from claim 29 they, too, must be free from the art. Applicants respectfully believe that the rejections are overcome and request reconsideration and withdrawal of the rejections.

VII. Obviousness-type double patenting

At pages 5-6 of the Office Action, it is asserted that claim 29 is an obvious variant of claims 1-11 of the ‘510 patent. Applicants respectfully traverse this rejection, because it

relies on the same misconstruction of claim 29 discussed above, in the context of anticipation. The claims of the '510 patent are not obvious variants of a properly-construed claim 29, in which full weight is given to the preamble. Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Applicants respectfully believe that all rejections and objections are overcome, and that all claims under examination are allowable. Applicants further request that the Examiner rejoin and examine withdrawn claims 30, 32, 33, 37 and 40.

The Examiner is invited to contact the undersigned if it believed that such communication would facilitate examination of the application.

The Commissioner is hereby authorized to credit any overpayment, or charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or any missing fees, to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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